DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 419, and 489

[CMS-1159-P]

RIN 0938-AK54

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2002 Payment Rates

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and changes arising from our continuing experience with this system. In addition, it would describe proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2002.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on [Insert 40 days after the date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1159-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1159-P,

P.O. Box 8017,

Baltimore, MD 21244-8017

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivery.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201, or

Room C5-16-03,

7500 Security Boulevard,

Baltimore, MD 21244-1850

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received too late for us to consider them.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

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FOR FURTHER INFORMATION CONTACT:

George Morey (410) 786-4653, for provider-based issues; and Nancy Edwards (410) 786-0378, for all other issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments:

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21244-1850 on Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call (410) 786-7195 or (410) 786-4668.

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To assist readers in referencing sections contained in this document, we are providing the following table of contents.

Outline of Contents

Addenda

Addendum A--List of Ambulatory Payment Classifications (APCs) with Status Indicators, Relative Weights, Payment Rates, and Copayment Amounts

Addendum B-—Payment Status by HCPCS Code, and Related Information

Addendum C--Hospital Outpatient Payment for Procedures by APC: Displayed on Website Only

Addendum D-—Payment Status Indicators for the Hospital Outpatient Prospective Payment System

Addendum E--CPT Codes Which Would Be Paid Only As Inpatient Procedures

Addendum G--Service Mix Indices by Hospital: Displayed on Website only

Addendum H--Wage Index for Urban Areas

Addendum I--Wage Index for Rural Areas

Addendum J--Wage Index for Hospitals That Are Reclassified

Alphabetical List of Acronyms Appearing in the Proposed Rule

APC	Ambulatory payment classification
APG	Ambulatory patient group
ASC	Ambulatory surgical center
AWP	Average wholesale price
BBA 1997	Balanced Budget Act of 1997
BIPA 2000	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
BBRA 1999	Balanced Budget Refinement Act of 1999
CAH	Critical access hospital
CAT	Computerized axial tomography
CCI	Correct Coding Initiative
CCR	Cost center specific cost-to-charge ratio
CMHC	Community mental health center
CMS	Centers for Medicare & Medicaid Services (Formerly known as the Health Care Financing Administration)
CORF	Comprehensive outpatient rehabilitation facility
CPI	Consumer Price Index
CPT	(Physician's) Current Procedural Terminology, Fourth Edition, 2001, copyrighted by the American Medical Association
DME	Durable medical equipment

DMEPOS	DME, prosthetics (which include prosthetic devices and implants) orthotics, and supplies
DRG	Diagnosis-related group
EMTALA	Emergency Medical Treatment and Active Labor Act
FDA	Food and Drug Administration
FQHC	Federally qualified health center
HCPCS	Healthcare Common Procedure Coding System
HHA	Home health agency
ICD-9-CM	International Classification of Diseases, Ninth Edition, Clinical Modification
IME	Indirect medical education
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MRI	Magnetic resonance imaging
MSA	Metropolitan statistical area
NECMA	New England County Metropolitan Area
OPPS	Hospital outpatient prospective payment system
PPS	Prospective payment system
RFA	Regulatory Flexibility Act
RHC	Rural health clinic
RRC	Rural referral center
SCH	Sole community hospital
SNF	Skilled nursing facility

I. Background

A. Authority

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), enacted on December 21, 2000, made further changes in the OPPS. The BIPA provisions that affect the OPPS are summarized below, in section I.C. The OPPS was first implemented for services furnished on or after August 1, 2000.

B. Summary of Rulemaking

• On September 8, 1998, we published a proposed rule (63 FR 47552) to establish in regulations a PPS for hospital outpatient services, to eliminate the formula-driven overpayment for certain hospital outpatient services, and to extend reductions in payment for costs of hospital outpatient services. On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographic errors in the September 1998 proposed rule including the proposed amounts and factors used to determine the payment rates.

• On April 7, 2000, we published a final rule with comment period (65 FR 18438) that addressed the provisions of the PPS for hospital outpatient services scheduled to be effective for services furnished on or after July 1, 2000. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. These outpatient services are classified according to a list of ambulatory payment classifications (APCs). The April 7 final rule with comment period also established requirements for provider departments and provider-based entities and prohibited Medicare payment for non-physician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under arrangement. In addition,

this rule extended reductions in payment for costs of hospital outpatient services as required by the BBA of 1997 and amended by the BBRA of 1999. Medicare regulations governing the hospital OPPS are set forth at 42 CFR 419.

• On June 30, 2000, we published a notice (65 FR 40535) announcing a delay in implementation of the OPPS from July 1, 2000 to August 1, 2000.

• On August 3, 2000, we published an interim final rule with comment period (65 FR 47670) that modified criteria that we use to determine which medical devices are eligible for transitional pass-through payments. The August 3, 2000 rule also corrected and clarified certain provider-based provisions included in the April 7, 2000 rule.

• On November 13, 2000, we published an interim final rule with comment period (65 FR 67798). This rule provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. We also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.

C. Summary of Relevant Provisions of the BIPA

The BIPA, which was enacted on December 21, 2000, made the following changes to the Act relating to OPPS.

1. Accelerated Reduction of Beneficiary Copayment

Section 111 amended section 1833(t)(8)(C) of the Act to limit the national copayment rate for OPPS services to 57 percent of the OPPS payment rate for services furnished in 2001 on or after April 1, 2001; 55 percent for services in 2002 and 2003; 50 percent for services furnished in 2004; 45 percent for services furnished in 2005; and 40 percent for services furnished in 2006 and thereafter.

Section 111 also specifies that nothing in BIPA 2000 or the Act, shall be viewed as preventing a hospital from waiving the amount of any beneficiary coinsurance for outpatient hospital services that may have been increased as a result of implementation of the OPPS.

2. Revision of Payment Update

Section 401 amended section 1833(t)(3)(C) of the Act to provide in 2001 an update equal to the full rate of increase in the market basket index. The 2002 update factor remains as it was under the law before the enactment of BIPA, that is, the market basket index percentage increase minus 1 percentage point.

3. Process and Standards for Determining Eligibility of Devices for Transitional Pass-Through Payments

Section 402 amended section 1833(t)(6) of the Act to require that the determination of eligibility for transitional pass-through payments be based on categories of devices (previously, eligibility was determined on a device-specific basis). The establishment of an initial set of categories was required effective for services furnished on or after April 1, 2001. This provision was implemented on March 22, 2001 in Program Memorandum (PM) No. A-01-41, which set forth a list of 96 initial categories.

Section 402 of the BIPA also provides that the Secretary must establish criteria to use in creating additional device categories. These criteria will be set forth in an interim final rule with comment period that will be published in the **Federal Register** at a later date.

Related to this issue is the issue of pro rata reductions of transitional pass through payments for new technology. A discussion of this can be found later in this document in Section VII. B.

4. Application of Transitional Corridor Payments to Certain Hospitals That Did Not Submit A 1996 Cost Report

Section 403 amended section 1833(t)(7)(F)(ii)(I) of the Act to allow transitional corridor payments to hospitals subject to the OPPS that did not have a 1996 cost report by authorizing the use of the first available cost reporting period ending after 1996 and before 2001.

5. Treatment of Children's Hospitals

Section 405 amended section 1833(t) of the Act to give

children's hospitals the same permanent hold harmless protection as cancer hospitals under the OPPS.

6. Transitional Pass-Through Payment for Temperature Monitored Cryoablation

Section 406 amended section 1833(t)(6)(A)(ii) of the Act to include devices of temperature monitored cryoablation as eligible for transitional pass-through payments. This provision will be included in the interim final rule concerning changes in eligibility of devices for transitional pass-through payments mentioned above.

7. Contrast Enhanced Diagnostic Procedures

Section 430 amended section 1833(t)(2) of the Act to require that procedures that use contrast agents be classified in groups that are separate from those to which procedures not using contrast agents are assigned. We implemented this provision in PM No. A-01-73, issued on June 1, 2001. In addition, section 430 amended section 1861(t)(1) of the Act to expand the definition of drugs to include contrast agents effective for contrast agents furnished on or after July 1, 2001.

8. Other Changes

In addition to the provisions directly related to OPPS, BIPA included the following provisions that will

require revision in the services assigned to APCs in the OPPS:

- Section 102 amended section 1861(s)(2) of the Act to allow coverage of glaucoma screening for certain high risk individuals effective for services furnished on or after January 1, 2002.

- Section 104(d)(2) directed the Secretary to determine if HCPCS codes are appropriate to describe mammography that uses new technology. The Secretary has created these codes for 2002.

Throughout this proposed rule, we discuss these various provisions and the changes we are proposing to make in the OPPS for them.